Testimony of

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of
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on behalf of
TEVA PHARMACEUTICALS USA, INC.

Concerning

H.R. 1902,

"Protecting Consumer Access to
Generic Drugs Act of 2007"

Before the

Subcommittee on Commerce, Trade, and Consumer Protection
of the
Committee on Energy and Commerce
of the
United States House of Representatives

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SUMMARY

- This testimony is submitted on behalf of Teva Pharmaceuticals USA, Inc., the largest *generic* pharmaceutical company in the US with probably the most experience with Hatch-Waxman Paragraph IV patent challenges.

- Based on its considerable experience with Hatch-Waxman litigation, Teva strongly believes that settlements of those cases are an absolutely necessary part of the Hatch-Waxman process and that it is essential to have an adequate range of terms over which to bargain to reach necessary and pro-consumer settlements like those in which Teva has engaged.

- Teva's settlements have brought major benefits to consumers by making possible the present and future launch of products an aggregate of 83.4 years before the expiration of relevant patents, thereby saving consumers more than $67 billion. H.R. 1902 as currently drafted would ban settlement terms that have enabled Teva to bring generic drugs to market years before they might otherwise have become available to consumers.

- Teva does not believe that legislation like that embodied in H.R. 1902 is necessary or desirable. However, recognizing the concerns raised by the FTC and in Congress with respect to perceived anticompetitive abuses in particular settlements, Teva has worked and will continue to work with members and staff in both houses of Congress to develop and refine legislative options that do not severely restrict the kinds of settlements that help to bring products to market for the benefit of consumers.

- The outcome of pharmaceutical patent litigation may be more uncertain today than it has been in the past and the need for the flexibility to settle when circumstances warrant is more important than ever.

- Alternative forms of legislation providing for review of settlements before they become effective, either by the court handling the patent litigation or by the FTC through a process similar to current Hart-Scott-Rodino merger review procedures, would be less potentially disruptive to the Hatch-Waxman process than a ban on particular kinds of settlement terms.

- H.R. 1902 imposes too stringent a limitation on settlements. At a minimum, it needs to be revised to allow for the kinds of settlements by which Teva has brought great benefits to consumers.

- The provisions of H.R. 1902 relating to forfeiture of the 180-day exclusivity for first filers are at least unnecessary and potentially very damaging to the core incentives underlying the Hatch-Waxman process.

Chairman Rush, Ranking Member Stearns, and members of the Subcommittee, good afternoon. My name is Ted Whitehouse and I am a partner in the law firm of Willkie Farr & Gallagher LLP, where I specialize in antitrust law and litigation. I have had the privilege of serving for several years as an antitrust lawyer for Teva Pharmaceuticals USA, Inc. ("Teva"), a leading pharmaceutical company that participates in both the generic and the branded sides of the industry. Teva appreciates the opportunity to appear and be heard on the important issues being considered here today.

Teva is in the business of bringing low-cost generic drugs to market as soon as possible. Teva believes that the ability to reach reasonable and pro-consumer settlements in Hatch-Waxman patent litigation is absolutely essential to Teva's efforts to bring low-cost generic drugs to market as soon as possible. From a consumer welfare standpoint, settlements that result in bringing products to market sooner and with more certainty than might otherwise have been the case are a good thing. As a practical matter, settlement is more likely to be achieved if the parties have the ability to bargain over a variety of terms than would be the case if the parties are forced to bargain over only one issue. Because H.R. 1902 would, in Teva's view, unduly restrict the terms over which parties to Hatch-Waxman litigation may bargain to reach a settlement, Teva does not support H.R. 1902 as currently drafted.

In the testimony that follows, I propose to elaborate on these points and focus on specific concerns with the proposed legislation. I will begin by noting that Teva believes that legislation providing for prior review of patent

settlements by a court or the Federal Trade Commission ("FTC") would be preferable to legislation categorically banning certain kinds of settlements. I will then explain how H.R. 1902 in its current form would unnecessarily ban some of the kinds of provisions that Teva has found to be necessary and useful in reaching pro-consumer settlements in the past. Finally, I will address briefly the provisions of H.R. 1902 that would amend the Food, Drug, and Cosmetics Act ("FDCA") so as to impose additional restrictions on the availability of the 180-day period of marketing exclusivity that is a crucial component of the incentive structure on which the entire Hatch-Waxman process depends.

I. TEVA AND ITS POSITION ON THESE ISSUES

Teva and its affiliates together constitute the largest *generic* pharmaceutical company in the world and the largest pharmaceutical company of any kind in the United States in terms of number of prescriptions filled. One result of that status is that Teva is the most active initiator of Paragraph IV Hatch-Waxman patent challenges and therefore has a lot of experience with litigating and settling the patent infringement cases that may result from challenging the patents on branded drugs. Based on that experience, Teva strongly believes that settlements of such cases are an absolutely necessary part of the Hatch-Waxman process. Teva's experience confirms that it is essential to have an adequate range of terms over which to bargain in order to reach necessary and pro-consumer settlements. Given that the parties are likely to disagree about the relative strengths of their respective cases, a negotiation for settlement limited to only one variable is highly likely to fail

because the parties will not be able to reach the agreement about the relative strength of their cases that is necessary to reach agreement on that one variable. The ability to negotiate over multiple variables increases the likelihood that the parties' differences can be bridged.

Teva believes that the Hatch-Waxman process is today working very well under the existing law as interpreted by the courts. The process is producing the savings to consumers, third-party payers, and the government that it was supposed to produce. Teva does not believe that legislation of the sort reflected in H.R. 1902 is necessary or desirable and is, therefore, opposed to H.R. 1902. However, Teva is very aware that there is strong sentiment in Congress and elsewhere that some action by Congress is needed to address perceived anticompetitive abuses in particular settlements. Teva has therefore been working and plans to continue to work constructively with members and staff of both houses of Congress in an effort to ensure that legislation motivated by a desire to ban what are perceived as bad settlements does not also ban good, necessary, and publicly beneficial settlements.

II. THE HATCH-WAXMAN PROCESS

The Hatch-Waxman amendments to the FDCA were intended to promote the introduction of low-cost generic drugs for the benefit of consumers. A central feature of those amendments is a process that enables generic drug companies to challenge the patents claimed to protect brand-name drugs. That process is designed to encourage generic companies to incur the expense and risk of designing around patents or facing patent litigation by

certifying to a belief that the branded drug company's patents are not a legitimate obstacle to generic competition, either because the generic company's proposed product does not infringe or because the patents are invalid or unenforceable. That is called a Paragraph IV certification. The Hatch-Waxman amendments offer the first generic company to make a Paragraph IV certification a 180-day period of marketing exclusivity as an inducement to identify opportunities to enter into the market before the expiration of the brand company's patents listed in the Food and Drug Administration ("FDA") Orange Book.

Under the Hatch-Waxman amendments, the making of a Paragraph IV certification often results in a patent infringement lawsuit being brought by the branded company against the generic company. Because patent litigation is expensive and can consume a large amount of the time of key company personnel -- and the resources of generic companies are, of course, finite -- generic companies must have the flexibility to reevaluate their position in Paragraph IV litigations as those cases proceed. Such reevaluation may lead reasonably to the conclusion that the prospects for success, when balanced against the costs of litigation and the other potential products to which the resources being consumed by the litigation might more productively be directed, are such that the case should be settled.

III. TEVA'S EXPERIENCE WITH HATCH-WAXMAN LITIGATION

Teva has probably been involved in more Hatch-Waxman Paragraph IV litigation than any other generic company and therefore has

substantial experience with litigating and settling such cases. Teva has litigated many cases but Teva believes that it is essential that it be able to settle these cases where appropriate. Taking away the ability to settle and redirect efforts to other, more promising alternatives will make certain generic companies less willing to commit to Paragraph IV patent challenges with respect to some products. That result would be detrimental to consumers' interests in timely availability of generic drugs.

Teva's experience makes clear that it is not easy to settle Paragraph IV cases. An artificial and unnecessarily restrictive limit on the terms available to be negotiated in such settlements will increase the likelihood that cases will be litigated rather than being settled on terms that are more favorable to consumers than a loss by the generic company.

Since 1999, Teva has either launched its generic product without waiting for a final court decision (what is known in the industry as launching "at-risk") or launched pursuant to a settlement 29 products on which it was the first generic firm to challenge the branded company's patent. In 19 of those cases, Teva launched at risk and, in the remaining 10 cases, Teva launched its product on the basis of a settlement. In the 19 at-risk launches, Teva brought products to market an aggregate of 200 years before patent expiration and saved consumers approximately $161 billion. In the 10 cases involving settlements, all of which provided for entry earlier than the expiration of the patents, Teva's settlements have made possible the past and future launches of products an aggregate of 83.4 years before patent expiration and brought and

will bring over $67 billion in savings to consumers. In five of its ten settlements, Teva brought its product to market in the same year as the settlements were reached. In four of its settlements, Teva secured the additional consumer benefit of early market entry on a product not at issue in the litigation being settled.

A settlement of the Paragraph IV litigation can often be the most pro-consumer outcome available to a generic company. Any settlement that produces some form of early entry is going to be preferable from a consumer perspective to a loss of the litigation by the generic company and the consequent delay of entry until the patent expires. As noted above, some of Teva's settlements have produced results that could not have been obtained from litigating the case to judgment, such as (1) early entry on products in addition to the one in suit, (2) protection for consumers in the event that the brand company undertakes to convert the market to another product, and (3) obtaining a comprehensive release and covenant not to sue covering all patents on the product at issue, not just the patent in suit, thereby assuring entry without further litigation.

One argument that has sometimes been advanced in the recent discussions about patent settlements is that generic companies are so likely to win Paragraph IV challenges that they have no good reason to settle. That argument is typically based on statistics showing that, in the early years of Hatch-Waxman litigation, generic companies won over 70 percent of such cases. If that statistic was ever true, it is certainly not so today.

Paragraph IV cases today involve more difficult issues than they typically did a few years ago and may be more difficult for generic companies to win. Paragraph IV litigation used to be primarily focused on issues of infringement but, in recent years, the predominant issues involve validity of the patents. In 1999, only 18 percent of Teva's Paragraph IV litigations were primarily focused on invalidity issues and 82 percent of those cases were focused primarily on issues of noninfringement. By contrast, in 2005, those percentages literally flipped, with invalidity cases accounting for 86 percent of the total and noninfringement cases accounting for 14 percent. That is very significant because, in general, invalidity cases are more difficult to win than are noninfringement cases. Also, an increasing proportion of the cases being litigated involve challenges to the basic compound patent rather than intrinsically easier issues involving more peripheral patents. During this same period, Teva believes that brand companies have become more sophisticated in their patenting and patent litigation strategies. What this means is that there is greater uncertainty about the outcome when Paragraph IV litigation is initiated than there used to be and a greater need to be able to reassess and move on to other more promising opportunities when events in the litigation make that advisable.

IV. POTENTIAL LEGISLATIVE ALTERNATIVES REGARDING PATENT SETTLEMENTS

As Teva understands the situation, the introduction of H.R. 1902 and the convening of this hearing today reflect a concern that some settlements of Paragraph IV Hatch-Waxman litigation have not been procompetitive or in

consumers' best interests. To the extent that there is a problem that requires legislative attention, Teva is aware of at least two broad categories of solutions that have been advanced to address it. The first category of solutions would involve establishing formal procedures to ensure that some responsible public official or agency has an opportunity and an obligation to evaluate the competitive effects of a proposed settlement before it becomes effective. The second category of solutions -- exemplified by H.R. 1902 -- would categorically ban certain kinds of settlements.

A. Formal Court or Agency Review Procedures

The first category of potential measures to address the perceived problem of bad patent settlements -- and the one that seems least likely to disrupt the existing and successful Hatch-Waxman process -- involves mechanisms to ensure that settlements are reviewed by a court or administrative agency to ensure that they conform to the standards already established in the antitrust, patent, and Food and Drug laws. One approach that has been suggested would be for the court before which the litigation being settled is pending to have an explicit mandate to review the settlement to ensure that it is lawful. The court before which the case is pending is particularly likely to be in a good position to know the relative strength of the parties' respective cases and to assess whether the settlement reasonably reflects that and other relevant factors.

An alternative or supplement to court review would involve more formal review processes before the FTC. Already, as a result of the 2003 MMA

amendments,[1] all settlements of Paragraph IV Hatch-Waxman litigation are now required to be filed with the FTC and the Antitrust Division of the Department of Justice. In Teva's experience, all such agreements are carefully reviewed by lawyers and economists at the FTC. A potential legislative approach that has been suggested would be for the FTC to have a more formal and structured review process for patent settlements, perhaps involving procedures similar to the Hart-Scott-Rodino procedures that have long governed large corporate mergers.[2] Under that kind of process, parties to a settlement of a Paragraph IV litigation would have to file their settlement agreement and it would not become effective for a reasonable period of time so as to let the FTC review it before it was actually carried out by the parties.

Teva believes that, if Congress concludes that legislation is needed to address bad settlements of Paragraph IV litigation, serious consideration ought first to be given to establishing mechanisms to ensure that all settlements are given timely review by the courts or the FTC. Teva believes that such mechanisms could adequately and non-disruptively address any perceived problems with bad patent settlements. Teva and others have previously suggested draft legislative language that would establish such mechanisms.

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[1] Pub. L. No. 108-173, 117 Stat. 2066 (2003).

[2] 15 U.S.C. § 18a (2007); 16 C.F.R. §§ 801-803 (2007).

B. Comments and Suggestions on H.R. 1902

H.R. 1902, like similar legislation pending in the Senate,[3] would broadly prohibit certain kinds of patent settlements (so-called "reverse-payment" settlements), subject to limited exceptions. The legislation would broadly ban any settlement in which any form of benefit flows to or through the generic company with only limited exceptions. Among other things, this means that all ten of the pro-consumer Teva settlements that I described earlier as having brought 83.4 years of time off the relevant patents and over $67 billion in savings to consumers would probably have been prohibited had H.R. 1902 been the law.

The legislative approach reflected in H.R. 1902 implicitly assumes that the parties to Paragraph IV litigation can reach pro-consumer settlements with only a very limited number of terms over which to bargain -- essentially, limited only to an agreement to entry on some date prior to the expiration of the patent in issue and waiver of damages for launches at risk that precede an unfavorable judgment in the patent litigation. Teva's experience is that restricting the terms of a potential settlement too narrowly will reduce the likelihood that any settlement will be reached and will thus create an undesirable risk that entry will not occur at all before patent expiration. Teva strongly urges that any legislation in this area at least allow for the sorts of pro-consumer settlements to which Teva has been a party.

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[3] S. 316, 110th Cong. (1st Sess. 2007)

As currently drafted, H.R. 1902 would allow a settlement to be based on early entry only with respect to the patent and product in suit. That limitation is likely to be a significant problem for at least two reasons.

First, as a litigator I can tell you that it is typical for the parties on opposite sides of litigation to have very different views of the strength of each of their cases. In those circumstances, a negotiation for settlement limited to only one variable has a high likelihood of failure because the parties will not be able to reach the consensus about the strength of their respective cases necessary to agree on that one variable. The ability to work with more variables increases the likelihood that the parties' differences can be bridged.

Second, branded drug companies often have strategic reasons that have nothing to do with the merits of the pending patent infringement lawsuit for refusing absolutely to negotiate entry as to the product in suit earlier than a date that is too late for fully competitive entry as to that product. Under those circumstances, a settlement based only on the entry date prescribed by the brand company for the product in suit would make little sense but a settlement providing also for early entry on some other product might make for a commercially sensible settlement that is in the best interests of consumers.

H.R. 1902 desirably provides for settlements to include a waiver of damages for prior marketing of the ANDA drug. We understand this provision to be intended to address, for example, the situation in which a generic company launches at risk on the basis of a favorable lower court decision and then finds it necessary to settle following an unfavorable ruling on appeal.

Teva has had actual experience with such a situation and strongly supports making provision for it in any legislation on this issue. However, Teva's experience suggests that broader language is necessary to make clear that settlements may permissibly include a complete release and covenant not to sue as to all patents on the product in suit so as to eliminate the risk that the branded company will settle and then later brandish other patents not asserted in the initial suit as a means to forestall generic entry. Also, consistently with the point as to other drug products in the time-off-the-patent provision, above, Teva believes that the release provision should clearly allow a full release and covenant not to sue as to such other products.

As many of those present are well aware, branded drug companies have recently adopted a strategy of releasing so-called "authorized generics" during the 180-day period of market exclusivity provided by the Hatch-Waxman law to the first filer of a Paragraph IV ANDA. The purpose and effect of such product releases by the branded companies are to diminish the value of the 180-day first-filer exclusivity to generic companies with the obvious goal of discouraging generic companies from pursuing the patent challenges that the Hatch-Waxman amendments were designed to encourage. To mitigate the effects of this undesirable practice, Teva believes that any legislation on these issues should specifically allow the parties to a settlement of a Paragraph IV litigation to agree through the means of an exclusive license for a limited duration that the branded company will not engage in this undesirable practice. Such a license is, of course, permissible under the current law.

Section 3 of H.R. 1902 contemplates FTC rulemaking to establish other potential carve-outs from the general prohibition. Teva supports that idea but also believes that it would be desirable to give the FTC specific authority to approve settlements on a case-by-case basis, notwithstanding the general prohibition, to avoid undue delay and to ensure that pro-competitive settlements are not blocked.

V. PROVISIONS OF H.R. 1902 RELATING TO FORFEITURE OF EXCLUSIVITY

In addition to the provisions directed to settlements of Paragraph IV Hatch-Waxman litigation, Section 4 of H.R. 1902 contains proposed amendments to core provisions of Hatch-Waxman amendments codified in the FDCA. Those proposed amendments to Hatch-Waxman are not limited to -- or necessarily related to -- settlements, and Teva believes that they could have substantial negative effects on the carefully balanced incentive structures that are at the very heart of the Hatch-Waxman process.

As noted previously in this testimony, the Hatch-Waxman amendments to the FDCA provide that a generic company that is the first to challenge a brand company's patent on a drug is entitled to 180 days of market exclusivity when it brings the generic product to market. The particular provisions of the FDCA that are proposed to be amended[4] are very complex and deal with the circumstances under which a generic company entitled to 180 days of first-to-file exclusivity may lose, or forfeit, that exclusivity. It is important to note at

[4] 21 U.S.C. § 355(j)(5)(D)(i) (2007).

the outset that the law as it exists today already addresses the situation in which a settlement agreement is held to be unlawfully anticompetitive: Under that circumstance, exclusivity is already required to be forfeited.[5]

Teva understands that the first proposed amendment -- proposed new subsection CC -- is intended to address a problem that no longer requires attention. That problem arose from case law in the United States Court of Appeals for the Federal Circuit that did not allow district courts to entertain certain declaratory judgment actions in cases in which generic companies filed Paragraph IV challenges to brand company patents and the brand companies refused either to sue or to promise not to sue over those patents. In the 2003 Medicare Modernization Act, Congress tried to make clear that declaratory judgment relief should be available to the generic company in that circumstance,[6] but the Federal Circuit held that declaratory judgment relief was not available due to constitutional limits on the jurisdiction of the federal courts. In technical terms, the Federal Circuit ruled that the courts did not have subject matter jurisdiction over such claims.[7] In January of this year, the United States Supreme Court ruled that the Federal Circuit's "reasonable apprehension of imminent suit" standard for subject matter jurisdiction in

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[5] 21 U.S.C. § 355(j)(5)(D) (2007).

[6] Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

[7] *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 405 F.3d 990 (Fed. Cir. 2005).

declaratory judgment cases was not consistent with the Constitution,[8] and the Federal Circuit has acknowledged that the courts may no longer refuse to hear declaratory judgment cases relating to patents listed in the Orange Book.[9] Thus, the concern to which this provision is directed is no longer a live concern. Given the potential for unintended consequences and unpredictable mischief that seems to inhere in all provisions of this complicated law, Teva strongly recommends that Congress not adopt this unnecessary provision.

The second proposed amendment to the forfeiture provisions of the FDCA -- captioned subsection DD -- seems to contemplate stripping the first filer of an ANDA of the exclusivity it has earned if some other applicant for authority to make the same generic drug purchases or otherwise obtains from the branded company and files with the FDA a covenant not to sue. The circumstances under which that would be a fair and appropriate result are not apparent to Teva.

CONCLUSION

Teva appreciates the opportunity to be heard today and welcomes the opportunity to maintain a continuing and constructive dialogue on these important issues with Members and their staffs.

Thank you.

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[8] *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 772-774 (2007).

[9] *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, No. 06-1181, 2007 WL 942201, at *11 (Fed. Cir. 30 Mar. 2007); *cf. Sandisk Corp. v. STMicroelectronics, Inc.*, No. 05-1300, 2007 WL 881008, at *7 (Fed. Cir. 26 Mar. 2007).